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March 20, 1999

Ms. Corey Tylka
FDA / CDRH / HFZ-323
2098 Gaither Road
Rockville, MD 20850

Dear Ms. Tylka,

I am writing to request a variance for a new Laser Tweezer Model under Section 1040.10 of the 21 CFR. The variance request is to eliminate the remote interlock from the design.

The Laser Tweezer is a Class IIIB laser that is designed to be directed through an objective lens on a microscope for the purpose of optical trapping. The Laser is mounted on a stationary work station in a laboratory setting

The design incorporates the required safety features, including a keyswitch, a beam attenuator and safety interlocks. The safety interlocks are design to insure that the laser is inoperable if it is ever removed from the microscope.

Attached is an artist rendering of the design, with the beam path for the laser indicated with red. As you can see, the beam path is directed in such a way that no laser radiation is directed into the room, and is only directed through the lens towards the target. Because the beam is contained in such a manner, there is no need for a remote interlock.

Thank you for your assistance.

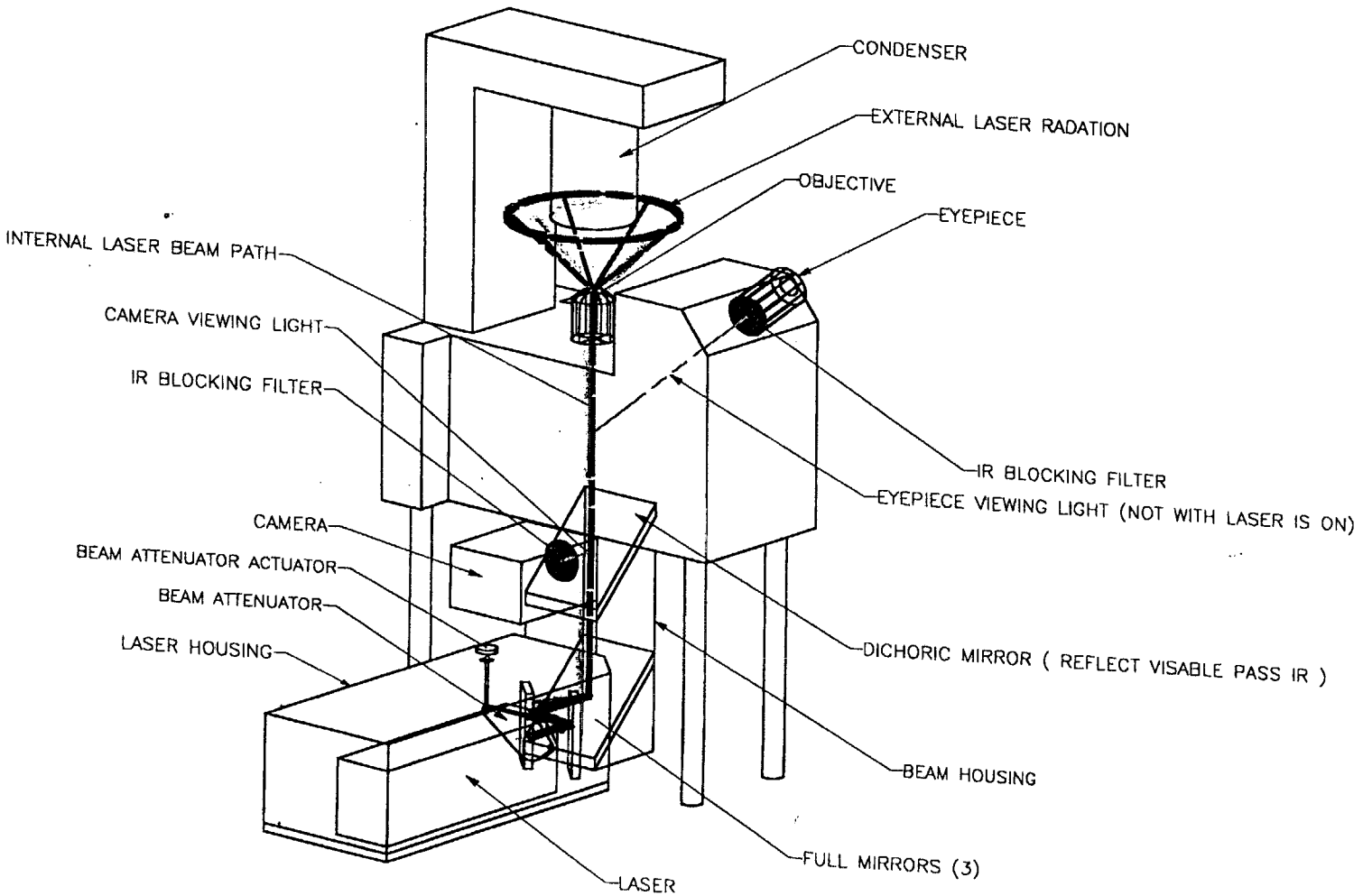
Sincerely,

C. White

Connie White

99V-0771

VAR 1


CONDENSER
EXTERNAL LASER RADATION
OBJECTIVE
EYEPIECE
INTERNAL LASER BEAM PATH
CAMERA VIEWING LIGHT
IR BLOCKING FILTER
IR BLOCKING FILTER
EYEPIECE VIEWING LIGHT (NOT WITH LASER IS ON)
CAMERA
BEAM ATTENUATOR ACTUATOR
BEAM ATTENUATOR
LASER HOUSING
DICHORIC MIRROR (REFLECT VISABLE PASS IR)
BEAM HOUSING
FULL MIRRORS (3)
LASER